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**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

DR. REDDY'S LABORATORIES INC.,

Plaintiff,

v.

AMARIN PHARMA, INC., AMARIN  
PHARMACEUTICALS IRELAND LIMITED,  
and AMARIN CORPORATION PLC,

Defendants.

Civil Action No. 21-10309  
(ZNQ)(LHG)

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Motion Day: January 3, 2022

(Filed Electronically)

**DEFENDANTS' BRIEF IN SUPPORT OF  
THEIR MOTION TO DISMISS**

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Defendants Amarin Pharma, Inc., Amarin Pharmaceuticals Ireland Limited, and Amarin Corporation plc (collectively, “Amarin”) submit this Brief in Support of their Motion to Dismiss the Complaint in this action filed by Plaintiff Dr. Reddy’s Laboratories Inc. (“DRL”).

## **INTRODUCTION**

Amarin has been selling its branded drug Vascepa® in the United States since 2012. Several generic manufacturers recently received FDA approval to sell generic versions of Vascepa, including DRL, which received approval in August 2020. DRL admits that it did not contact potential suppliers to assess the availability of supply for the active ingredient in Vascepa for its launch until April to May 2020, a few months before the FDA approved DRL’s product. DRL alleges that it ultimately obtained supply of the active pharmaceutical ingredient (“API”) of Vascepa (as did another generic manufacturer, Hikma), but obtaining that supply took longer than DRL would have liked. DRL claims that this “delay” was due to Amarin’s contractual relationships with its API suppliers, which DRL describes as exclusive or de facto exclusive arrangements.

But what DRL’s lawsuit actually reflects is its own failure to plan ahead to obtain the API supply it now claims to need. DRL’s own complaint concedes that it did not reach out to potential API suppliers to line up launch quantities until just a few months before it received FDA approval, and it is not surprising that suppliers

by then were committed to others. This lawsuit is therefore about a competitor that did not take any advance steps to develop the supply chain for its commercial launch and operated as though it could obtain supplies on short notice without doing any of the necessary preparations.

None of this amounts to an antitrust violation by Amarin. The antitrust laws recognize the benefits that flow from committed supply arrangements, such as ensuring steady sources of supply, promoting stable, long-term business relationships and encouraging manufacturers to invest in creating and expanding suppliers. As a result, such arrangements are generally presumed lawful—and procompetitive—under the antitrust laws. DRL has not alleged sufficient facts to subject Amarin to antitrust liability for engaging in this normal and customary practice in the marketplace to ensure a steady supply of the API for Amarin’s product.

As reflected in Amarin’s public SEC filings, on which DRL liberally relies in its Complaint, Amarin has made significant investments in its suppliers over the past decade to expand supply of Vascepa’s API.<sup>1</sup> DRL does not allege that it has made any similar investments to create or expand any supplier of API for its generic version of Vascepa. Nor does DRL allege that the raw material from which the API is made is scarce. DRL in fact acknowledges its slipshod planning for its launch—

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<sup>1</sup> See note 2, *infra*.

that it checked in with Amarin's existing suppliers only a few months before receiving FDA approval, and that those suppliers not surprisingly were already committed to Amarin. Nothing stopped DRL from taking the same steps as Amarin to plan ahead to develop supplier relationships so that DRL could have had access to the amount of supply it wanted at the time of its launch. And DRL in fact *was* able to obtain the supplies needed for its launch—but a few months later than it wanted.

Nothing in the antitrust laws now requires Amarin to turn over to DRL the supply chain that Amarin built, working hand-in-hand with its suppliers. As a result, DRL's Complaint should be dismissed in its entirety.

### **BACKGROUND**

Amarin is the manufacturer of Vascepa, a prescription medicine used to reduce the risk of heart attack, stroke, and certain other types of cardiovascular issues. Compl. ¶¶ 37–39. The FDA approved Vascepa in 2012 for lowering triglyceride levels in patients with very high triglycerides. *Id.* ¶ 38. After many years of investment and a substantial follow-on clinical trial, the FDA approved an additional indication for Vascepa in 2019 for the reduction of cardiovascular risk in certain high-risk patients, including those resistant to statin therapy. *Id.* ¶ 39. This new indication allows Amarin to reach many more patients beyond the original indication for Vascepa. The new indication is subject to data exclusivity that does

not expire until December 13, 2022 (*id.*)—a protection the FDA affords clinical trial data that prevents generic drug manufacturers from relying on such data in submissions to the agency for product approval. Amarin has also secured approvals or positive recommendations to sell Vascepa in the European Union, the United Kingdom, Canada, and certain countries in the Middle East, and is pursuing regulatory approvals to sell the drug in China, among other countries.<sup>2</sup>

The API for Vascepa is icosapent ethyl, which is a form of eicosapentaenoic acid (“EPA”), an omega-3 fatty acid derived from fish oil. *Id.* ¶ 37. As the Complaint reflects, manufacturers of EPA must engage in an isolation and separation process for fish oil to create high purity, pharmaceutical-grade EPA to meet the product specifications for Vascepa. *Id.* ¶ 51. Amarin’s API suppliers include Novasep, Nisshin, BASF, Chemport [REDACTED]. *Id.* ¶¶ 57, 61. The Complaint cites to Amarin’s SEC filings to describe the contractual relationships between Amarin and its API suppliers. *See, e.g., id.* ¶¶ 54, 59. But the Complaint ignores the portions of those same SEC filings that detail the significant investments that

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<sup>2</sup> *See* Amarin Corp. plc, Annual Report (Form 10-K), at 2 (Feb. 25, 2021); Amarin Corp. plc, Quarterly Report (Form 10-Q), at 9 (Nov. 5, 2020); Amarin Corp. plc, Annual Report (Form 10-K), at 6-7 (Mar. 3, 2015). These SEC filings disclose facts not subject to reasonable dispute and were cited in the Complaint at footnotes 4, 10, and 12, respectively. *See Winer Fam. Tr. v. Queen*, 503 F.3d 319, 327 (3d Cir. 2007) (court should consider “documents incorporated into the complaint by reference, and matters of which a court may take judicial notice”); *In re Amarin Corp. PLC Sec. Litig.*, 2021 WL 1171669, at \*8 (D.N.J. Mar. 29, 2021) (“The Third Circuit permits a district court to judicially notice SEC filings and public disclosures.”).

Amarin has made in its suppliers to increase the available capacity of EPA for Vascepa, given that most fish-oil-derived products do not require EPA of the level of purity required for Vascepa.<sup>3</sup>

Several drug manufacturers have sought FDA approval to market a generic version of Vascepa, including Hikma and DRL. *Id.* ¶ 44. When Vascepa’s new indication was approved in 2019, both Hikma and DRL carved out the 2019-approved indication from their labels. *Id.* ¶ 45. Hikma and DRL subsequently received approvals in May 2020 and August 2020, respectively, and Hikma launched its product later that year (and clearly was able to obtain supply to support that launch). *Id.* ¶ 46. However, DRL claims that it had difficulties in lining up API supply on favorable terms. An API supplier with which DRL allegedly [REDACTED]

[REDACTED]. *Id.* ¶ 67. Moreover, instead of agreeing to [REDACTED]  
[REDACTED] *Id.*

DRL alleges that it [REDACTED]  
[REDACTED]

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<sup>3</sup> See, e.g., Amarin Corp. plc, Annual Report (Form 10-K), at F-29 (Mar. 3, 2015) (noting \$16 million in payments to its suppliers for certain development fees, raw material purchases, and supply commitments); Amarin Corp. plc, Quarterly Report (Form 10-Q), at 27 (Aug. 8, 2013) (noting a commitment to its suppliers of up to \$3.3 million for development fees and \$5.3 million in payments to a supplier for “stability and technical batches and advances on future API purchases”). These SEC filings were cited in the Complaint at footnotes 12 and 21, respectively and are properly considered by the Court on this Rule 12 motion. See note 2, *supra*.

[REDACTED]. *Id.* ¶ 60. [REDACTED]  
 [REDACTED] *Id.* ¶ 63. DRL notes that it  
 also engaged an unnamed “additional alternative API supplier” [REDACTED]  
 [REDACTED]. *Id.* ¶ 84. DRL makes no allegations that it could not have engaged  
 with this “alternative” supplier [REDACTED]—rather than waiting to  
 engage until the month *after* DRL received FDA approval for its generic product.

Although DRL lined up two API suppliers [REDACTED]  
 [REDACTED], DRL asserts that its entry into the market  
 was delayed by “at least 10 months” (*id.* ¶ 79), or possibly “more than a year” (*id.*  
 ¶ 9) or even “potentially as long as 3 years” (*id.* ¶ 62).

DRL asserts a claim of unlawful concerted action under Sherman Act Section  
 1 and Section 2 claims of monopolization and attempted monopolization on the  
 alleged basis that “Amarin entered into exclusive or de facto exclusive agreements  
 with at least four leading suppliers of icosapent ethyl API—BASF, Novasep,  
 Chemport, and Nisshin—who are also the only suppliers with sufficient capacity to  
 support a timely commercial launch without having to first expand capacity.” *Id.*  
 ¶ 114.<sup>4</sup> DRL also asserts claims under the New Jersey Antitrust Act, as well as a

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<sup>4</sup> For purposes of this Rule 12 motion only, Amarin accepts as true DRL’s allegation that it has entered into “exclusive” or “quasi-exclusive” supply arrangements with certain suppliers.

common law unfair competition claim and a claim for tortious interference with contract or prospective economic benefit.

### LEGAL STANDARD

To survive a motion to dismiss, a plaintiff must plead factual allegations sufficient “to raise a right to relief above the speculative level.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). Doing so “requires more than labels and conclusions” or “a formulaic recitation of the elements of a cause of action.” *Id.* Even factual allegations need not be credited where they “are belied by . . . the remaining factual allegations” of the complaint. *Schuylkill Energy Res., Inc. v. Pa. Power & Light Co.*, 113 F.3d 405, 417 (3d Cir. 1997).

Each of DRL’s antitrust claims requires well-pleaded allegations that Amarin “engaged in anti-competitive or exclusionary conduct.” *Barr Labs., Inc. v. Abbott Labs.*, 978 F.2d 98, 112 (3d Cir. 1992); *see Schuylkill*, 113 F.3d at 413 (same).<sup>5</sup> “Courts employ either a *per se* or a rule of reason analysis to determine whether conduct is anticompetitive,” *Eisai*, 821 F.3d at 402, and DRL does not—and could not—argue that Amarin’s conduct is anticompetitive *per se*. Consequently, DRL’s allegations of anticompetitive conduct are subject to the rule of reason. *See Jame Fine Chems., Inc. v. Hi-Tech Pharm. Co.*, 2007 WL 927976, at \*4 (D.N.J. Mar. 27,

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<sup>5</sup> *See also Verizon Commc’ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 407 (2004) (monopolization claim requires “an element of anticompetitive conduct”); *Eisai, Inc. v. Sanofi Aventis U.S., LLC*, 821 F.3d 394, 402 (3d Cir. 2016) (concerted action claim requires “anticompetitive conduct”).

2007) (“[V]ertical nonprice restraints of trade are evaluated in this Circuit under the full Rule of Reason analysis.”).

An exclusive supply agreement is unlawful under the rule of reason “only if the probable effect of the arrangement is to substantially lessen competition, rather than merely disadvantage rivals.” *Eisai*, 821 F.3d at 403. To evaluate the legality of such agreements, courts consider “whether a plaintiff has shown substantial foreclosure of the market for the relevant product,” and “the likely or actual anticompetitive effects of the exclusive dealing arrangement, including whether there was reduced output, increased price, or reduced quality in goods or services.” *Id.*

## ARGUMENT

### I. DRL’s Antitrust Claims Should Be Dismissed.

The Complaint fails to state a claim for violation of the Sherman Act because it does not allege anticompetitive conduct, antitrust injury or injury to competition. The state-law antitrust and unfair competition claims are deficient for the same reasons.<sup>6</sup>

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<sup>6</sup> Sections 56:9-3 and 56:9-4 of the New Jersey Antitrust Act are governed by the same tests as Section 1 and Section 2 of the Sherman Act, respectively. *See Eisai, Inc. v. Sanofi Aventis U.S., LLC*, 821 F.3d 394, 402 n.11 (3d Cir. 2016). Similarly, because DRL relies on the same conduct in support of its unfair competition claims as it does for its antitrust claims, the unfair competition claim is likewise deficient and should also be dismissed. *See C.R. Bard v. Wordtronics Corp.*, 561 A.2d 694, 696 (N.J. Super. Ct. Law Div. 1989) (“There is no distinct cause of action for unfair competition. It is a general rubric which subsumes various other causes of action.”); (continued...)

**A. Amarin’s Efforts to Secure a Steady Supply of API Do Not Support an Antitrust Claim.**

“[E]xclusive supply contracts [and] exclusive dealing agreements have been frequently upheld when challenged on antitrust grounds,” given the procompetitive benefits of such arrangements. *Race Tires Am., Inc. v. Hoosier Racing Tire Corp.*, 614 F.3d 57, 76 (3d Cir. 2010) (collecting cases). “[I]n many circumstances,” exclusivity provisions “may be highly efficient” because they can “assure supply, price stability, outlets, [and] investment ... and pose no competitive threat at all.” *Id.* (quoting *E. Food Servs., Inc. v. Pontifical Catholic Univ. Servs. Ass’n, Inc.*, 357 F.3d 1, 8 (1st Cir. 2004)).

To meet its pleading burden, DRL must allege that the “arrangement would have anti-competitive effects outweighing the legitimate economic advantages that it might provide.” *E. Food Servs.*, 357 F.3d at 5 (affirming dismissal under Rule 12(b)(6) of exclusive contract claim). DRL’s allegation that Amarin has exclusive or “de facto exclusive” contracts with its suppliers that provide Amarin with “sufficient or excess” supply does not meet this burden. Amarin has a legitimate interest in securing “sufficient” supply of its product’s key ingredient, and the

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*see also Juice Ent., LLC v. Live Nation Ent., Inc.*, 2012 WL 2576284, at \*5 (D.N.J. July 3, 2012) (“[O]utside the intellectual property context, [unfair competition and unlawful interference with a contractual relationship] are not independent causes of action.”).

antitrust laws do not impose a duty on Amarin to share with its competitor the supply chain that Amarin has created.

**1. DRL’s Allegations Reflect Amarin’s Pro-Competitive Efforts to Secure a Steady Supply of a Key Ingredient.**

DRL’s allegation that Amarin secured “sufficient” supply of API for Vascepa through exclusive supply arrangements is fully consistent with robust competition in the market for Vascepa and its generic equivalents. Antitrust law recognizes that “the great majority of output contracts are at least presumptively procompetitive.” P. Areeda & H. Hovenkamp, *Antitrust Law* ¶ 1803a (4th ed. 2019); *see Pickett v. Tyson Fresh Meats, Inc.*, 420 F.3d 1272, 1280 (11th Cir. 2005) (defendant’s supply arrangements were “unquestionably legitimate” because they “provide[d] the company with a reliable and stable supply of cattle for its packing plants”).

Thus, courts have routinely recognized the benefits of committed supply arrangements, which “assure supply” for the buyer and “protect[] against price fluctuations and offer the possibility of a predictable market” for the seller. *Tampa Elec. Co. v. Nashville Coal Co.*, 365 U.S. 320, 333–34 (1961); *see also E. Food Servs., Inc.*, 357 F.3d at 8 (describing the benefits of exclusive dealing arrangements); *Menasha Corp. v. News America Marketing In–Store, Inc.*, 354 F.3d 661, 663 (7th Cir. 2004) (competition to be an exclusive supplier may constitute “a vital form of rivalry, and often the most powerful one, which the antitrust laws encourage rather than suppress”); *Sewell Plastics, Inc. v. Coca-Cola Co.*, 720 F.

Supp. 1196, 1219 (W.D.N.C. 1989) (exclusive supply agreement that included limitation on supplier selling to other buyers was procompetitive where the supplier was “assured of a ready market for its products” and where buyer had invested equity to assist supplier in building a new plant and agreed to certain minimum purchase amounts), *aff’d*, 912 F.2d 463 (4th Cir. 1990).

DRL’s allegations fall squarely within these legitimate and pro-competitive purposes of exclusive supply arrangements. As the Complaint alleges, Amarin is facing growing demand for its product. *See* Compl. ¶ 88. And a firm with growing demand for its product naturally seeks a “reliable and stable” supply of that product’s key ingredient. *Pickett*, 420 F.3d at 1282. Furthermore, as reflected in the SEC documents DRL cites in the Complaint, Amarin has made extensive investments in building this supply chain, a well-recognized basis for committed supply arrangements. *See* note 3, *supra*; *Sewell Plastics, Inc.*, 720 F. Supp. at 1219.

Against this backdrop, despite DRL’s conclusory characterization of Amarin’s “anticompetitive strategy to lock up the supply” of API, Compl. ¶ 43, DRL has alleged nothing more than a series of efforts by Amarin to build the supply chain for Vascepa and to meet the growing market demand for that medicine. EPA is a “critical input to manufacturing” Vascepa, a drug that Amarin held the exclusive right to manufacture until March 2020. *Id.* ¶¶ 2, 45. Vascepa has been approved to reduce triglyceride levels since 2012, and was approved for a significant new

indication in 2019. *Id.* ¶¶ 38-39. As the Complaint itself discloses, after approval of this indication—to reduce cardiovascular risks for certain high-risk patients—“the demand for Icosapent Ethyl Drug Products,” such as Vascepa, “continues to increase.” *Id.* ¶ 88.

As a result, DRL’s allegation that Amarin has secured its supply of API through committed supply arrangements does not meet DRL’s burden to allege that the “arrangement[s] would have anti-competitive effects outweighing the legitimate economic advantages that [they] might provide.” *E. Food Servs., Inc.*, 357 F.3d at 5. This is especially the case because DRL pleads no facts to plausibly suggest that Amarin would have made its significant investments in the API supply chain without these committed arrangements. In other words, DRL does not allege that Amarin would have made these investments to build the robust API supply that now exists on a global scale without the alleged exclusivity provisions in certain of the supply agreements.

DRL’s other allegations do not change this conclusion. The allegation that Amarin’s supply arrangements must be anticompetitive because it is “industry practice” for a manufacturer to have only “one to two API suppliers,” Compl. ¶ 76, does not withstand scrutiny. The number of API suppliers required by a manufacturer in the pharmaceutical industry (as in any other industry) depends on many factors such as the complexity and scarcity of the ingredient in question, the

volume each supplier is capable of providing, and the business risks associated with relying on a small number of suppliers. Engaging multiple suppliers helps drug makers “mitigate [the] risk” associated with reliance on a single supplier, and thus “qualify[ing] multiple suppliers for pharmaceutical products” is common within the industry. *Endo Pharms. Inc. v. Amneal Pharms., LLC*, 224 F. Supp. 3d 368, 385-86 (D. Del. 2016).<sup>7</sup>

At bottom, DRL’s complaint is that Amarin should have given DRL access to the API supply chain that Amarin took years to build. *See, e.g.*, Compl. ¶ 61 (“generic manufacturers like DRL ordinarily use API suppliers with existing DMFs and just reference the DMF in their ANDAs”). But, DRL could have (and eventually did) develop its own supply of API. There is no principle clearer in the antitrust laws than the notion that a company has no duty to help its competitor or to share supply arrangements (or other infrastructure) that it has built for its own needs. The Supreme Court has stated the point clearly: “[T]here is no duty to aid competitors,” and companies may properly “establis[h] an infrastructure that renders them uniquely suited to serve their customers. Compelling such firms to share the source of their advantage is in some tension with the underlying purpose of antitrust law,

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<sup>7</sup> DRL also alleges that some of Amarin’s supply agreements contain provisions providing for cash payments to a supplier if there are any shortfalls in Amarin’s minimum purchase obligations. Compl. ¶ 59. There is nothing unlawful about this standard contract provision, and, in any event, DRL does not allege that any such provisions have ever been triggered.

since it may lessen the incentive . . . to invest in those economically beneficial facilities.” *Verizon Commc’ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 407–08 (2004). *See also Mylan Pharms. Inc. v. Warner Chilcott Public Limited Co.*, 838 F.3d 421, 432 (3d Cir. 2016) (affirming dismissal of antitrust claims where district court had found that “Defendants [brand companies] have no duty to facilitate [the generic’s] business plan”). This settled principle requires dismissal of DRL’s Complaint.

## **2. The Complaint’s “Excess Supply” Allegations Are Implausible.**

DRL’s failure to plausibly plead that Amarin’s supplier relationships and resulting contracts were entered into for anticompetitive reasons is not bolstered by DRL’s allegation that the arrangements provided “sufficient *or excess*” API supply to Amarin. *See, e.g.*, Compl. ¶¶ 145, 179 (emphasis added).<sup>8</sup> DRL focuses its allegations on the notion that because, according to DRL, Amarin “already ha[s] sufficient or *an excess* of API supply from its existing suppliers,” it has no valid reason to order more. *Id.* (emphasis added). These conclusory allegations overlook an “obvious alternative explanation” for Amarin’s orders. *See Twombly*, 550 U.S. at 567. In particular, the obvious explanation for Amarin’s redoubled efforts to

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<sup>8</sup> Amarin has contemporaneously filed a Motion for Sanctions against DRL requesting that the Court strike DRL’s allegations that Amarin was purchasing an “excess supply” of Vascepa API that it did not need. If the Court grants that motion, the “excess supply” allegations are moot, and the Court need not address the implausibility of those allegations.

secure API supplies is the increased demand for Vascepa based on its recent FDA approval for a second indication and continued worldwide approvals for Vascepa. *See* Compl. ¶ 88.<sup>9</sup>

To the extent the Complaint alleges otherwise, it does so without a plausible basis. Consider, for example, DRL’s assertion that Amarin’s orders ██████ ██████ could not have been to “ensure adequate supplies.” *Id.* ¶ 77. Amarin already had “four exclusive suppliers lined up,” the Complaint asserts, and so its ██████ ██████ could not have been necessary because “the entire market for Vascepa in the United States is estimated to require 450 metric tons of icosapent ethyl API per year.” *Id.* Setting aside that DRL pleads no supporting factual allegations for its bare assertion regarding the size of the U.S. market, it is a matter of public record that Amarin sells Vascepa not just in the United States, but also sells or is planning to sell Vascepa in the European Union, the United Kingdom, mainland China, Hong Kong, Macau and Taiwan as well as the Middle East and North Africa.<sup>10</sup> Amarin’s needs for API supply should be considered in light of the worldwide demand for Vascepa, not an estimate of U.S. demand, and the

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<sup>9</sup> *See* Amarin Receives FDA Approval of VASCEPA® (icosapent ethyl) to Reduce Cardiovascular Risk (Dec. 13, 2019), <https://www.prnewswire.com/news-releases/amarin-receives-fda-approval-of-vascepa-icosapent-ethyl-to-reduce-cardiovascular-risk-300974860.html> (describing five-year clinical trial). This press release was cited in the Complaint at ¶ 42 n.5 and is therefore properly considered by the Court on this Rule 12 motion. *See* note 2, *supra*.

<sup>10</sup> *See* note 2, *supra*.

Complaint's disregard for that obvious fact renders its excess supply allegations implausible.

Similarly, the Complaint's assertion that "Amarin's public statements in December 2018 confirmed that it had enough API supply for at least two years," Compl. ¶ 77, is just as implausible. DRL pleads no factual support for the source of this allegation. That claim is apparently based solely on a December 2018 post on the website Smartkarma, which publishes blog posts written by anonymous "independent third party research and content providers."<sup>11</sup> Such baseless assertions are not well-pleaded factual allegations, especially where the Complaint provides no basis for crediting the source and the blog post in question "does not cite any source at all for its version of events." *In re AOL, Inc. Repurchase Offer Litig.*, 966 F. Supp. 2d 307, 311, 314 (S.D.N.Y. 2013) (dismissing complaint and declining to credit allegations based on pseudonymous blog post).

In short, DRL's allegations that Amarin is purchasing an "excess supply" of API are implausible and lack any adequate factual basis. And when these unsupported "excess supply" allegations are stripped from the Complaint, *see Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009), DRL is left only with its allegation that

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<sup>11</sup> See Smartkarma, <https://www.smartkarma.com/home/faqs/>. Amarin's pending Rule 11 motion (Dkt. 36) further demonstrates why DRL could not properly rely on this anonymous blog post to support the allegations of its Complaint.

Amarin has sourced “sufficient” supply for its product, which does not state a plausible antitrust claim.

**B. DRL’s Delayed Identification of Suitable API Suppliers Is Not an Antitrust Injury.**

In addition to its inability to allege anticompetitive conduct by Amarin, DRL’s Sherman Act claims should also be dismissed because DRL’s alleged delays in identifying and qualifying a suitable API supplier do not constitute an antitrust injury. Private plaintiffs in antitrust suits must allege “antitrust injury, which is to say injury of the type the antitrust laws were intended to prevent and that flows from that which makes defendants’ acts unlawful.” *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977); accord *Ethypharm S.A. France v. Abbott Labs.*, 707 F.3d 223, 233 (3d Cir. 2013). The failure to adequately allege antitrust injury mandates dismissal of the Complaint. See, e.g., *Phila. Taxi Ass’n, Inc v. Uber Techs., Inc.*, 886 F.3d 332, 343–45 (3d Cir. 2018).

To plead antitrust injury, “a plaintiff must show harm to competition, not just harm to the plaintiff competitor.” *Race Tires Am., Inc. v. Hoosier Racing Tire Corp.*, 614 F.3d 57, 83 (3d Cir. 2010). Under this well-settled rule, antitrust injury cannot be alleged by a private plaintiff simply “averring that it would have fared better without the defendant’s alleged conduct.” *Phila. Taxi*, 886 F.3d at 343; see *Cargill, Inc. v. Monfort of Colo., Inc.*, 479 U.S. 104, 116 (1986) (“[C]ompetition for increased market share[] is not activity forbidden by the antitrust laws.”).

The Third Circuit’s decision in *Race Tires America* illustrates the rule. There, a race tire supplier sued its rival, alleging that its rival’s exclusive supply agreement with certain racing organizations violated the antitrust laws. 614 F.3d at 62–72. The plaintiff there was indisputably harmed by its rival’s conduct, as it was prevented from supplying tires for drivers in thousands of races. *Id.* at 62–63. Yet there was no antitrust injury because the plaintiff “had the clear opportunity to compete and did compete, sometimes successfully, for the exclusive tire contracts” in connection with other races. *Id.* at 84; *see also Fleer Corp. v. Topps Chewing Gum, Inc.*, 658 F.2d 139, 140, 150 (3d Cir. 1981) (contracts with all major league players did not “exclude[] effective competition in the sale of baseball trading cards” because competitor had ability to sign minor league players). This distinction between harms to a competitor and harms to competition is also reflected in *Philadelphia Taxi*, where the Third Circuit upheld a dismissal for lack of antitrust injury because the complaint itself reflected robust competition. 886 F.3d at 343–45. There, taxi driver plaintiffs saw “a decline in ridership, and loss of medallion value” as a result of Uber’s entry into the market, but there was no antitrust injury because the complaint reflected an “increased . . . number of vehicles-for-hire available to consumers . . . , thereby increasing competition.” *Id.* at 344.

DRL’s allegations, even accepted as true, do not assert the required “harm to competition” and thus do not state an antitrust claim. Taking the allegations of the

Complaint as true, DRL (a) failed to contact API suppliers to discuss launch quantities until three or four months before FDA approval of its product, (b) refused to [REDACTED] and (c) [REDACTED] and from an “additional alternative API supplier” within five months of first seeking out any suppliers. Compl. ¶¶ 46, 60, 67, 84. On these facts, even assuming DRL is right that Amarin has committed supply arrangements that “lock up” various sources of supply, DRL has not suffered an antitrust injury because it was able to obtain API supply. Its failure to plan ahead to line up suppliers more than a few months before FDA approval is not an “injury of the type the antitrust laws were intended to prevent” but is instead injury caused by its own poor planning. For instance, even crediting DRL’s point that it was able to line up two suppliers within five months of first asking, DRL would have avoided any delay if it had simply engaged in advance planning a few months earlier. Its failure to do so cannot form the basis of an antitrust claim.

In other words, DRL’s allegations of antitrust injury are “belied by ... the remaining factual allegations” of the Complaint. *Schuylkill Energy*, 113 F.3d at 417. DRL alleges that the key ingredient of Vascepa and any generic form of the drug—EPA—is derived from fish oil and is closely related to compounds such as the API for omega-3-acid ethyl esters. Compl. ¶ 51. According to DRL, the “raw input” for these two compounds, as well as the “facilities, technologies, and manufacturing

lines and equipment used to extract and purify [them] from fish oil are largely the same,” and “there is no shortage of supply” of the other compound. *Id.* ¶¶ 51, 70. Consequently, as the Complaint candidly acknowledges, “suppliers of fish oil-based drugs can easily switch capacity to produce [EPA].” *Id.* ¶ 51. DRL simply did not move quickly enough to line up supply, and it failed to invest in the planning process needed to establish the supply that it concedes is available with advance planning.

According to DRL, the problem is that “this ease of switching in terms of manufacturing process does not directly translate to ease of supply of [API].” *Id.* ¶ 52. The Complaint alleges that this is because drug makers must reference a supplier’s Drug Master File (“DMF”) when seeking approval to manufacture a drug, and a new supplier of API would need to submit a new DMF. *Compl.* ¶ 52. But every competitor in the market for Vascepa and its generic equivalents must either identify an existing supplier of API or submit a new DMF for a new API supplier. Thus, the costs of identifying and qualifying suppliers of key pharmaceutical ingredients are an inherent feature of competition in the industry and are borne by all manufacturers of Vascepa and its generic equivalents. *See Fleeer*, 658 F.2d at 150 (fact that competitor’s minor league players may take “several years” to reach majors was “a characteristic of major league baseball, rather than an illegal restraint of trade”).

The lack of injury to competition is further demonstrated by the Complaint’s allegation that drug manufacturer Hikma obtained FDA approval for a generic version of Vascepa in May 2020 and launched the product later that year. Compl. ¶ 46. In the six months between the launch and the filing of DRL’s Complaint, Hikma obtained a “12% share of the . . . Market.” *Id.* ¶ 94. DRL, for its part, successfully obtained approval for its generic version of Vascepa by identifying a

[REDACTED]

[REDACTED].

*Id.* ¶¶ 61, 80. DRL also located a third “additional alternative API supplier . . . to support its launch” of generic Vascepa. *Id.* ¶ 84. DRL’s own allegations therefore make clear that Amarin’s alleged conduct did not impair competition.

DRL’s complaint is that it did not obtain API supply as quickly as it would have liked. But DRL alleges no facts to demonstrate why it could not have begun the process to line up API suppliers sooner, as part of the advance planning for the launch of its product. DRL clearly failed to plan ahead, but that is not an antitrust issue. In fact, DRL’s Complaint effectively acknowledges DRL’s failure of planning—DRL makes no allegations that it initially contacted any potential suppliers other than Amarin’s current suppliers to identify launch quantities of API. And DRL identifies no efforts that it has made (unlike Amarin) to invest in expanding the capacity of any potential supplier. *See id.* ¶ 114 (“Amarin entered

into exclusive or de facto exclusive agreements with at least four leading suppliers of icosapent ethyl API—BASF, Novasep, Chemport, and Nisshin—who are also the only suppliers with sufficient capacity to support a timely commercial launch *without having to first expand capacity.*”) (emphasis added).

In short, all DRL has alleged is competition between DRL, Amarin and other drug makers for an ingredient in great demand. DRL “had the clear opportunity to compete and did compete, sometimes successfully,” to obtain that supply. *Race Tires*, 614 F.3d at 84. And DRL’s failure to plan ahead—it did not even begin contacting prospective suppliers until a few months before FDA approval—is not antitrust injury. This lack of antitrust injury is fatal to its antitrust claims.

**C. DRL Pleads at Most a Transitory Injury Insufficient to Create Antitrust Liability.**

Moreover, DRL has alleged at most a transient injury to competition that is not cognizable under the Sherman Act, providing an independent ground for dismissal of the Complaint. “While ‘every commercial agreement restrains trade,’ only restraints causing substantial adverse effects on marketwide competition are cognizable under the federal antitrust laws.” *Procaps S.A. v. Patheon Inc.*, 141 F. Supp. 3d 1246, 1277–78 (S.D. Fla. 2015) (quoting *Nw. Wholesale Stationers v. Pacific Stationery & Printing Co.*, 472 U.S. 284, 289 (1985)), *aff’d*, 845 F.3d 1072 (11th Cir. 2016); *see Eichorn v. AT&T Corp.*, 248 F.3d 131, 140 (3d Cir. 2001) (an antitrust plaintiff must demonstrate “a wider impact on the competitive market”). A

Sherman Act claim requires “a preliminary showing of significant and *more-than-temporary* harmful effects on competition.” *Adaptive Power Sols., LLC v. Hughes Missile Sys. Co.*, 141 F.3d 947, 952 (9th Cir. 1998) (emphasis added). As a result, a temporary reduction in competition, such as a “temporary decline in the number of competitors,” is “not significant enough to be classified as an injury to competition under the Sherman Act.” *Id.*

Cases applying this rule abound. In *Adaptive Power*, for example, the plaintiff alleged concerted action by defense contractors to force one of two suppliers out of the market. 141 F.3d at 948–49. Observing that the alleged reduction in competition created only a “four to ten-month lag in production” of the missile parts in question, the Ninth Circuit found no “injury to competition under the Sherman Act.” *Id.* at 952. Similarly, in *Jame Fine Chemicals, Inc. v. Hi-Tech Pharmacy Co.*, the court considered allegations by a generic drugmaker that an ingredient shortage “resulted in the complete absence of any generic competition” for certain cough syrups. 2007 WL 927976, at \*5 (D.N.J. Mar. 27, 2007). Noting the alleged shortage “lasted only between five and nine months,” the court concluded that was “not a sufficiently substantial foreclosure of the relevant market.” *Id.*; *see also Fleeer*, 658 F.2d at 150 (even though “it would be several years” before a competitor could produce a “marketable product,” this “simply identifies a characteristic of [the industry], rather than an illegal restraint of trade”); *Williamsburg Wax Museum, Inc. v. Historic*

*Figures, Inc.*, 810 F.2d 243, 251–52 (D.C. Cir. 1987) (finding no monopoly power in market for “display figures for wax museums” where plaintiff admitted it had located a second supplier, though “the second supplier could not deliver figures for a year”); *Procaps*, 141 F. Supp. 3d at 1281 (“The seven-month duration of the restraint is also far too short as a matter of law to create the required substantial marketwide harm of actual detrimental effects.”).

Here, DRL has alleged at most a transient injury. To begin, the Complaint purports to allege that DRL’s entry into the market for a generic version of Vascepa “has been substantially delayed by at least 10 months,” Compl. ¶ 79, a period of time that falls comfortably within the period deemed a merely transitory injury by other courts. *See Williamsburg Wax Museum*, 810 F.2d at 251 (one year); *Adaptive Power*, 141 F.3d at 951–52 (four to ten months).

Just as important, DRL’s “ten month” claim is contradicted by the factual allegations of the Complaint. After the Vascepa patents were invalidated in March 2020, DRL reached out [REDACTED]. Compl. ¶ 60. DRL’s generic version of Vascepa was approved by the FDA in August 2020. *Id.* ¶ 46. And by September 2020, [REDACTED] an “additional alternate . . . supplier” had agreed to provide API to DRL. *Id.* ¶ 84. Thus, DRL’s own allegations that it had suppliers in place by September—a month after its FDA approval—directly contradicts its assertion of a “ten month delay.” And even more

to the point, the fact that DRL by its own allegations did not contact a single supplier before April-May 2020 to line up launch quantities—just months before FDA approval of its generic version of Vascepa—exposes that the issue here is DRL’s failure to plan ahead for its launch. The modest delays that DRL alleges—even if they are attributed to Amarin’s conduct rather than DRL’s own failure of planning—fall well short of a “substantial adverse effect[] on marketwide competition,” and thus require dismissal of DRL’s antitrust claims. *Procaps*, 141 F. Supp. 3d at 1277–78.<sup>12</sup>

## **II. DRL’s Tortious Interference Claim Should Be Dismissed.**

To state a claim for tortious interference with contract or prospective economic advantage under New Jersey common law, a plaintiff must show: “(1) it had a continuing or prospective economic relationship or reasonable expectation of economic advantage; (2) the defendant knew of such relationship of expectancy; (3) the interference and harm inflicted were done intentionally and with ‘malice’ in the sense of conduct that is wrongful and without justification or excuse; (4) if not for the interference, it was reasonably probable that plaintiff would have realized its economic advantage; and (5) the plaintiff was injured as a result of defendant’s conduct.” *Reckitt Benckiser Inc. v. Tris Pharma, Inc.*, 2011 WL 773034, at \*7

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<sup>12</sup> DRL’s claims of delays lasting “more than a year” or even “potentially as long as 3 years,” *e.g.*, Compl. ¶¶ 62, 79, are simply bare assertions, unsupported by any factual allegations, that cannot support its antitrust claim.

(D.N.J. Feb. 28, 2011) (quoting *Fineman v. Armstrong World Indus., Inc.*, 980 F.2d 171, 186 (3d Cir. 1992)); *see also Printing Mart-Morristown v. Sharp Elecs. Corp.*, 563 A.2d 31, 37 (N.J. 1989). DRL’s allegations of tortious interference with its relationship [REDACTED], and its allegations of prospective benefit from selling generic Vascepa to third parties, are each insufficient to state a claim under this legal standard.

**A. DRL Fails to Adequately Allege Amarin Tortiously Interfered with DRL’s Contract [REDACTED].**

DRL alleges that by signing a supply agreement [REDACTED], Amarin has tortiously interfered with DRL’s contract with or prospective economic benefit from its relationship [REDACTED]. Compl. ¶¶ 168-172. But DRL falls well short of pleading a viable tortious interference claim for a number of reasons.

*First*, DRL lacks well-pleaded allegations that Amarin knew of DRL’s contract [REDACTED]. “Actual knowledge of the contract with which a defendant supposedly interfered is a prerequisite to making out a claim for tortious interference.” *Mylan Inc. v. SmithKline Beecham Corp.*, 723 F.3d 413, 422 (3d Cir. 2013); *see also Matrix Distributors, Inc. v. Nat’l Ass’n of Boards of Pharmacy*, 2020 WL 7090688, at \*16 (D.N.J. Dec. 4, 2020) (dismissing tortious interference claims because, among other reasons, the allegations did not support an inference of “actual knowledge and specific intent”). DRL’s allegation that Amarin was aware of DRL’s

contractual relationship [REDACTED] is conclusory and unsupported. *See* Compl. ¶ 171.

To the extent that DRL pleads any basis for this allegation, it is that “through discovery in Amarin’s patent litigation with DRL, [REDACTED]

[REDACTED] *Id.* The materials DRL refers to are subject to the discovery confidentiality order in the patent litigation, and that order precludes the use of any such materials “for any . . . other purpose.” *See* Discovery Confidentiality Order at 3, *Amarin Pharma Inc. v. Apotex Inc.*, 3:14-cv-02550-MLC-TJB (D.N.J.), December 1, 2014 (Dkt. 73). DRL has no basis to allege that Amarin violated the order by using confidential information [REDACTED] with DRL. *See CSL Silicones Inc. v. Midsun Grp. Inc.*, 2016 WL 3568173, at \*5 (D. Conn. June 27, 2016) (a court will “not lightly assume that parties will violate their obligations imposed on them by a duly entered order on the Court’s docket”). DRL’s allegation of Amarin’s “actual knowledge” [REDACTED] contract is thus not supported by well-pleaded factual allegations.

*Second*, DRL fails to allege Amarin acted with malice. Malice in tortious interference does not mean “ill will” toward the plaintiff, but rather harmful conduct that is “fraudulent, dishonest, or illegal.” *Ideal Dairy Farms, Inc. v. Farmland Dairy Farms, Inc.*, 659 A.2d 904, 933, 936 (N.J. App. Div. 1995). DRL alleges that

Amarin's orders [REDACTED]

[REDACTED] Compl. ¶ 172. But DRL's only allegation that Amarin's agreement [REDACTED] amounts to anything fraudulent, dishonest, or illegal is its claim that Amarin's conduct violates the antitrust laws. *See id.* ¶ 173. Because DRL has not alleged conduct in violation of the antitrust laws, *see* Section I, *supra*, it has also not alleged the malice required for its tortious interference claim. *See Ideal Dairy Farms, Inc.*, 659 A.2d at 935-36 (recognizing conduct that is "neither predatory nor restrictive of competition" "does not provide a basis for a claim of tortious interference").

*Third*, DRL fails to allege causation. To show causation, a plaintiff must allege that "if not for the interference, it was reasonably probable that plaintiff would have realized its economic advantage"—which requires "demonstrat[ing] a causal connection between the alleged interference and its loss." *Eli Lilly & Co. v. Roussel Corp.*, 23 F. Supp. 2d 460, 494 (D.N.J. 1998) (finding plaintiff "failed to assert a prima facie case of tortious interference" where plaintiff failed to demonstrate a causal connection between the alleged interference and its loss). Here, DRL argues that but for Amarin's "interference," [REDACTED] have declined to supply sufficient amounts of API to DRL. Compl. ¶¶ 174–75. While DRL repeatedly alleges it made "no economic sense" [REDACTED] to decline DRL's orders but [REDACTED] relationship with Amarin, its own Complaint demonstrates the

opposite. *See id.* ¶¶ 3, 69, 70, 175. DRL notes that “icosapent ethyl API provides more opportunity for suppliers to earn higher margins,” *id.* ¶ 70, and [REDACTED], *id.* ¶ 67. Accordingly, it *did* make economic sense [REDACTED]. Thus, on the face of the Complaint, DRL’s own allegations show that [REDACTED] that affected its alleged economic benefit.

**B. DRL Fails to Adequately Allege Amarin Tortiously Interfered with DRL’s Prospective Economic Benefit from Third Parties.**

DRL’s other tortious interference allegations are even more speculative. The Complaint claims that Amarin interfered with DRL’s reasonable expectation of prospective economic benefit from selling its generic version of Vascepa to unspecified third parties, Compl. ¶ 176, but it similarly fails to plead a number of required elements of a tortious interference claim.

*First*, DRL fails to allege a reasonable expectation of economic advantage. It is well-settled that tortious interference requires more than “a mere hope” that “customers would have been forthcoming.” *Novartis Pharms. Corp. v. Bausch & Lomb, Inc.*, 2008 WL 4911868, at \*7 (D.N.J. Nov. 13, 2008) (quoting *Advanced Power Sys., Inc., v. Hi-Tech Sys., Inc.*, 801 F. Supp. 1450, 1459 (E.D. Pa. 1992)). At the pleading stage, a plaintiff “must allege an injury that is more concrete than lost business of unknown, unsolicited, or hypothetical customers.” *Advanced Oral*

*Techs., L.L.C. v. Nutrex Rsch., Inc.*, 2011 WL 1080204, at \*4 (D.N.J. Mar. 21, 2011).

DRL has not done so here—it has not, for example, identified any particular customers or business opportunities, other than a desire to manufacture and sell a generic version of Vascepa. Instead, DRL advances a claim “based entirely on speculation and conjecture,” and its claim should be dismissed for that reason.

*Marin v. Landgraf*, 2013 WL 356623, at \*5 (D.N.J. Jan. 29, 2013).

*Second*, DRL fails to allege that Amarin knew of DRL’s alleged expectancy. Once a plaintiff establishes a reasonable expectation of economic benefit or advantage, it must demonstrate “the defendant’s knowledge of that expectancy.” *Lightning Lube, Inc. v. Witco Corp.*, 4 F.3d 1153, 1167 (3d Cir. 1993). Because a “plaintiff seeking to recover for tortious interference must show that the defendant specifically intended to interfere with *that* plaintiff,” the defendant “cannot be liable for interfering with [an expectancy] of which he or she was unaware.” *Id.* at 1170. DRL alleges that Amarin has been aware of DRL’s intention to market a generic version of Vascepa since at least July 2016, when DRL submitted its ANDA. Compl. ¶ 177. Even assuming this is true, only Amarin’s conduct *after* it knew of DRL’s supposed expectancy could support DRL’s tortious interference claim. Yet Amarin’s supply relationships with Nisshin, Chemport, BASF (formerly known as Equateq) and Novasep (as part of the Slamnhor consortium) all pre-date July 2016. *See* Compl. ¶¶ 57, 59. Therefore, DRL does not allege that Amarin knew of DRL’s

alleged relationship of expectancy at the time Amarin entered into its agreements with those suppliers for this reason, and the reasons set forth above.

*Third*, DRL does not allege that Amarin acted with malice. As detailed above, DRL's only allegation of malice depends on its claim that Amarin's conduct violated the antitrust laws. Because DRL has not adequately alleged an antitrust violation, it has not adequately alleged malice. Moreover, Amarin first entered into supply agreements with the "four leading suppliers" of API *before* DRL submitted its application to manufacture a generic version of Vascepa. Compl. ¶¶ 178–79. As a result, Amarin could not have acted "intentionally and with malice" toward DRL in signing these agreements. *Ideal Dairy Farms, Inc.*, 659 A.2d at 933, 936.

*Fourth*, for the same reasons as above, DRL fails to plead a causal connection between any interference and its alleged losses, given that Amarin's supply arrangements pre-dated any effort by DRL to sell its product to third parties and given DRL's own lackluster efforts to line up API supply. Compl. ¶¶ 180–81; *Fineman*, 980 F.2d at 186; *Eli Lilly & Co.*, 23 F. Supp. 2d at 494.

### CONCLUSION

For the reasons set forth above, the Complaint should be dismissed with prejudice for failure to state a claim.

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Respectfully submitted,

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